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Docket No.: 0327-0815-0

AF/1617

#23

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ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

RE: Application Serial No.: 09/468,777

Applicants: Keiko HASEBE, et al.

Filing Date: December 21, 1999

For: AMPHIPATIC LIPID DISPERSION

Group Art Unit: 1617

Examiner: WELLS, Lauren Q.

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SIR:

Attached hereto for filing are the following papers:

APPEAL BRIEF (In Triplicate)

Our check in the amount of **\$320.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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#23

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11/3/02

IN RE APPLICATION OF

Keiko HASEBE, et al. : EXAMINER: WELLS

SERIAL NO.: 09/468,777 : GROUP ART UNIT: 1617

FILED: DECEMBER 21, 1999 :

CPA Filed: November 20, 2001

FOR: AMPHIPATIC LIPID
DISPERSION :

APPEAL BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The following is an appeal of the Examiner's Final rejection of May 14, 2002 of claims 11-21 as obvious. A Notice of Appeal along with a petition for a one-month extension of time was filed on September 16, 2002.

REAL PARTY IN INTEREST

The real party in interest is Kao Corporation, by assignment recorded at reel/frame 010613/0121.

RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignee are not aware of any related appeals and interferences which will directly affect or be directly affected, or have a bearing on the Board's decision in the pending appeal.

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STATUS OF CLAIMS

Claims 11-21 are active in this application and are herein appealed.

STATUS OF AMENDMENTS

Two amendments have been made during prosecution. A first amendment canceling claims 1-10 and adding claims 11-19 was made and entered on May 14, 2001. A second amendment amending claims 11, 15 and 17-19 and adding claims 20-21 was made and entered on November 20, 2001.

A copy of the claims herein appealed, as presently amended, is attached as an appendix.

SUMMARY OF THE INVENTION

The present invention is directed to a dispersion of an amphipathic lipid as a solid particulate dispersed in a surfactant and aqueous medium (page 3, lines 5-23 of the specification).

Amphipathic lipids such as ceramide are reported as components in hair and skin compositions. Formulations of such materials in an amount greater than 2 wt.% can be difficult to prepare due to the melting temperature of these materials. Attempts to address this problem by dissolving the ceramide and then emulsifying have produced diminished effects. Accordingly, amphipathic lipid compositions of lipid which provide for improved concentration are sought.

The present invention addresses the problem by providing a dispersion of 5 to 40 wt.% of an amphipathic lipid dispersed in a surfactant and aqueous medium in which the amphipathic lipid has an average particle size of from 0.5 to 150 μm . Appellants have

discovered that such an amphipathic lipid dispersion provides for increased concentrations of lipid while retaining the desirable effects of the lipid. Such a dispersion is nowhere disclosed or suggested in the prior art of record.

ISSUES

- 1) Whether claims 11-21 are not patentable as obvious over *Nakamura et al.* E.P. 487,958 in view of *Vanlerberghe et al.* U.S. 5,985,255 or *Young* U.S. 4,152,272.
- 2) Whether claims 11-21 are not patentable as obvious over *Dubief et al.* U.S. 5,679,357 in view of *Vanlerberghe et al.* U.S. 5,985,255 or *Young* U.S. 4,152,272.
- 3) Whether claims 11-21 are not patentable as obvious over *Pillai et al.* U.S. 5,476,661 in view of *Vanlerberghe et al.* U.S. 5,985,255 or *Young* U.S. 4,152,272.
- 4) Whether claim 15, which uses the term "pseudo-ceramide," is definite within the meaning of 35 U.S.C. §112, second paragraph.

GROUPING OF CLAIMS

Appellants respectfully submit that the claims do not stand and fall together.

For the purposes of issue 1, the claims are grouped as follows:

- group 1, claims 11-15 and 21;
- group 2, claims 16 and 20; and
- group 3, claims 17-19.

For the purposes of issue 2, the claims are grouped as follows:

- group 1, claims 11, 14, 15, 17-19 and 21
- group 2, claims 12-13;
- group 3, claims 16 and 20

For the purposes of issue 3, the claims are grouped as follows:

group 1, claims 11-15 and 21;

group 2, claims 16 and 20; and

group 3, claims 17-19.

For the purposes of issue 4, claim 15 stands and falls alone.

ARGUMENTS

The examiner has rejected claims 11-21 as not patentable as obvious under 35 U.S.C. §103(a) over *Nakamura et al.* EP 487,958, *Dubief et al.* U.S. 5,679,357 and *Pillai et al.* U.S. 5,476,661 each in view of *Vanlerberghe et al.* U.S. 5985,255 or *Young* U.S. 4,152,272.

The examiner has committed reversible error by concluding the claimed invention to be obvious as the cited references fail to disclose or suggest the claim limitation of an amphipathic lipid being present as a solid particulate having an average particle size of from 0.5 to 150 μm , dispersed in a surfactant and aqueous medium.

Issue 1:

Nakamura et al. describe a composition in which the amphipathic lipid is present as an emulsion, containing a liquid dispersoid. The composition is prepared by mixing the amphipathic lipid (A), nonionic surfactant (B) and/or ionic surfactant (C). The lipid is not water soluble and is a **solid** at room temperature (page 2, lines 48-49). In this process, the lipid and surfactant components are melted together, **thereafter** the aqueous medium (D) is added, whereby an anisotropic **liquid** crystal phase is formed which, after cooling to room temperature, a lipid microdispersion is obtained (page 4, lines 18-20). The final result is a composition, in which the amphipathic lipid and surfactant are present as an anisotropic

liquid crystal phase and the lipid is contained in the composition in a clear transparent or semi-transparent condition (page 2, lines 29-30).

Group 1 Claims 11-15 and 21:

Claims 11-15 and 21 are not rendered obvious by the cited references as the references fail to teach the claim limitations of 1) the amphipathic lipid being present as a solid particulate having a particle size of 0.5 to 150 μm ; and 2) the amphipathic lipid being dispersed in the surfactant and aqueous medium.

Nakamura et al. fails to recite a particle size for the amphipathic lipid component (see Official action of January 3, 2002, page 2, last line). The examiner has cited the secondary references of *Vanlerberghe et al.* and *Young* as teaching compositions in which the particle size overlapped the claimed range of 0.5 to 150 μm and that it would have been obvious to have formulated the composition of *Nakamura et al.* to have a particle size within that claimed as the secondary references are also directed to compositions comprising wax, surfactant and an aqueous medium and all three references related to cosmetic compositions (Official action of January 3, 2002, at 4).

There is no motivation provided by the secondary references to formulate the composition of *Nakamura et al.* to have the amphipathic lipid present as a solid particulate of the claimed particle size, as *Nakamura et al.* teaches that the lipid and surfactant are to be melted together to form a new liquid crystal phase. Evidence that the amphipathic lipid is not present as a solid particulate having an average particle size of 0.5 to 150 μm is found in the reported phase change of the amphipathic lipid from being a solid, to existing as an anisotropic liquid crystal phase in conjunction with the surfactant. This actually teaches away from forming amphipathic lipid particles of the claimed particle size range, as the reference does not even suggest discrete particles of amphipathic lipid.

In contrast, the present invention is directed to a dispersion of amphipathic lipid as a solid particulate having an average particle size of from 0.5 to 150 μm , the solid particulate being dispersed in surfactant and aqueous medium. The claim limitation of the amphipathic lipid being a solid particulate of a particle size of 0.5 to 150 μm is a claim limitation which is not found in the cited references. Quite to the contrary the primary reference teaches formulation of the amphipathic lipid as an anisotropic liquid crystal phase with the surfactant.

Moreover, the reference fails to suggest dispersion of the amphipathic lipid in the surfactant and aqueous medium.

Nakamura et al. describes a very different structure from that claimed, in that the lipid and surfactant are melted, which **together** form an anisotropic liquid crystal phase. In such a structure the **lipid is not dispersed** in the surfactant and aqueous medium, but rather the lipid and surfactant have formed a new liquid crystal phase. Accordingly, the cited reference fails to teach the claim limitation of the amphipathic lipid being dispersed in the surfactant and aqueous medium. The examiner has committed reversible error in concluding the claimed invention to be obvious and accordingly, the decision of the examiner must be reversed.

As such, the primary reference, even in combination with the secondary references fails to disclose or suggest the claim limitations of 1) the amphipathic lipid being dispersed in surfactant and aqueous medium; and 2) the amphipathic lipid being present as a solid particulate having an average particle size of from 0.5 to 150 μm . In the absence of such teaching of these claim limitations, the examiner's conclusion of obviousness is not supported and must be reversed.

Group 2 Claims 16 and 20:

Claims 16 and 20 directed to a dispersion and a process of preparing a dispersion in which lipid, surfactant and aqueous medium are heated to not less than the melting point of the lipid are not suggested by the cited references.

As discussed above, *Nakamura et al* describes a process in which lipid and surfactant are melted together, **then** aqueous medium is added (page 4, lines 18-20). The aqueous medium is not added, until after the lipid and surfactant have been melted together. As such the reference fails to disclose or suggest a dispersion or process in which the lipid, surfactant and aqueous medium are heated together at not less than the melting point of the lipid. The claim limitation of the heating of the lipid, surfactant and aqueous medium, together to a temperature of not less than the melting point of the lipid is a claim limitation which is not found in the cited references and accordingly the claims of group 2 are not obvious.

Group 3 Claims 17-19:

A wash-away type cosmetic composition is nowhere disclosed or suggested in the cited references. *Nakamura* fails to disclose or suggest a cosmetic composition which is a wash-away type, in any way. As such the claims of group 3, claims 17-19 which recite that the composition is washed away is not made obvious by these references.

Issue 2

The claimed invention is not obvious over *Dubief et al.* in view of the secondary references of *Vanlerberghe et al.* and *Young* as there is no teaching of the lipid being present as a solid particulate of a particle size of 0.5 to 150 μm

Group 1 Claims 11, 14, 15, 17-19 and 21:

Dubief et al. simply describes a composition considered to be an emulsion. The reference describes formulation of the composition by forming a paste of the cationic

surfactant and ceramide, followed by melting the mixture at a temperature of about 80 °C (column 3, lines 38-41) Thereafter hot water is added, with vigorous stirring using an Ultraturrax. The result will be the production of an emulsion. Like Nakamura *et al.* described above, *Dubief et al.* describes a composition prepared by melting the surfactant and lipid, then adding water. The result is an emulsion and not a dispersion as claimed. There is no disclosure of the lipid being present as a solid particulate, as claimed. There is no disclosure of the lipid having an average particle size of from 0.5 to 150 μm .

In contrast, the present invention is directed to a dispersion of amphipathic lipid as a solid particulate having an average particle size of from 0.5 to 150 μm , the solid particulate being dispersed in surfactant and aqueous medium. The claim limitation of the amphipathic lipid being a solid particulate of a particle size of 0.5 to 150 μm is a claim limitation which is not found in the cited reference.

Dubief et al describes a very different structure from that claimed, in that the lipid and surfactant are melted, **together**. The lipid is **not dispersed** in the surfactant and aqueous medium, but rather the lipid and surfactant are melted together. The cited reference fails to teach the claim limitation of the amphipathic lipid being dispersed in the surfactant and aqueous medium. The examiner has committed reversible error in concluding the claimed invention to be obvious and accordingly, the decision of the examiner must be reversed.

Group 2 Claims 12 and 13:

The invention of claims 12 and 13, which recites that the surfactant is one of a nonionic, anionic, amphoteric surfactant is not rendered obvious by the cited reference which is specifically limited to cationic surfactants (column 2, line 25). Claims which recite anything but a cationic surfactant are not suggested or made obvious by the cited reference.

Group 3 Cclaims 16 and 20:

Claims 16 and 20 directed to a dispersion and a process of preparing a dispersion in which lipid, surfactant and aqueous medium are heated to not less than the melting point of the lipid are not suggested by the cited references.

As discussed above, *Dubief et al* describes a process in which lipid and surfactant are melted together, **then** aqueous medium is added (column 3, lines 38-43). The aqueous medium is not added until after the lipid and cationic surfactant have been melted together. As such the reference fails to disclose or suggest a dispersion or process in which the lipid, surfactant and aqueous medium are heated together at not less than the melting point of the lipid. The claim limitation of the heating of the lipid, surfactant and aqueous medium, together to a temperature of not less than the melting point of the lipid is a claim limitation which is not found in the cited references and accordingly the claims of group 3 are not obvious.

Issue 3:

Pillai et al. does not disclose any solid particles or particle size whatsoever.

Group 1 Claims 11-15 and 21:

The primary reference fails to disclose or suggest a composition in which the lipid is dispersed as a solid particulate in surfactant and aqueous medium and has a particle size of from 0.5 to 150 μm .

Since the reference fails to disclose or suggest solid particles of amphipathic lipid in any context, the reference can not suggest a dispersion in which the amphipathic lipid is a **solid particulate** and **dispersed** in a surfactant and aqueous medium. While the examiner has cited to the decision *In re Rose* as basis for the obviousness of selection of particle size, in the present case, the examiner presupposes that the reference of Pillai et al describes a particle of

lipid of any size. In fact, the reference fails to describe a composition in which an amphipathic lipid is a solid in a surfactant and an aqueous medium. As the reference fails to describe a composition in which the amphipathic lipid is in solid form, the reference can not suggest an amphipathic lipid as a solid particulate which is dispersed in surfactant and aqueous medium. Accordingly the claim limitation of the amphipathic lipid being a solid particulate is a claim limitation which is not found in the cited reference and accordingly the claimed invention can not be found to be obvious therefrom.

Group 2 Claims 16 and 21:

Claims 16 and 20 directed to a dispersion and a process of preparing a dispersion in which lipid, surfactant and aqueous medium are heated to not less than the melting point of the lipid are not suggested by the cited references.

As discussed above, *Pillai et al* fails to disclose or suggest a particle size for the lipid component in any fashion. With respect to this group of claims, the reference fails to suggest melting the lipid, surfactant and water together. The claim limitation of the heating of the lipid, surfactant and aqueous medium, together to a temperature of not less than the melting point of the lipid is a claim limitation which is not found in the cited references and accordingly the claims of group 2 are not obvious.

Group 3 Claims 17-19:

The reference fails to disclose or suggest a wash-away type cosmetic composition. Quite to the contrary the reference, at column 15, lines 27-39 describes a composition which is simply applied to the skin, nails or hair, thereby reducing the permeability of the surface to water. Such does not suggest a wash-away type cosmetic composition.

Issue 4:

Claim 15 has been rejected under 35 U.S.C. §112, second paragraph.

The metes and bounds of the term "psuedoceramide" is clear to those of ordinary skill in the art, as evidenced by the use of this term in claims of issued U.S. patents. Appellants have previously submitted a print out of a patent term search from the U.S.P.T.O. data base of patents issued from 1996 to 2002 in which the term "pseudoceramide" appears **in the claims**. Five patents were identified. The appearance of this term in issued U.S. patents is evidence that the term is understood by those of skill in the art.

Moreover, the very reference cited by the examiner of *Pillai et al.* uses the term "pseudoceramide" throughout the specification (e.g. column 4, line 31). As such the term is evidenced to be well known to those of ordinary skill in the art, such that the metes and bounds of the claimed invention is clear to those of ordinary skill in the art. The decision of the examiner must be reversed.

Appellants submit that in view of the deficiencies noted above, the decision of the primary examiner must be reversed.

Respectfully submitted,

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APPENDIX

11. A dispersion comprising:

(a) 5 to 40 wt.% of an amphipathic lipid having, in the molecule thereof, at least one hydroxy group and at least one amide group;

(b) 2 to 55 wt.% of a surfactant; and

(c) an aqueous medium,

wherein said amphipathic lipid has an average particle size of 0.5 to 150 μm as a solid particulate and is dispersed in said surfactant and aqueous medium.

12. The dispersion of claim 11, wherein said surfactant (b) is selected from the group consisting of a nonionic surfactant, an anionic surfactant, an amphoteric surfactant and a mixture thereof.

13. The dispersion of claim 12, wherein said nonionic surfactant is selected from the group consisting of a alkyl polyglycoside, a polyoxyalkylene alkyl ether, a polyoxyalkylene alkenyl ether, a polyoxyalkylene sorbitan fatty acid ester, a sorbitan fatty acid ester and a mixture thereof.

14. The dispersion of claim 11, wherein a component (a)/component (b) weight ratio ranges from 90/10 to 25/75.

15. The dispersion of claim 11, wherein component (a) is a substance pseudo-ceramide.

16. A process for preparing a dispersion as claimed in any one of claims 11 to 13, which comprises heating the component (a), the component (b) and water to a temperature not less than the melting point of the component (a), thereby fusing them; and cooling to crystallize the component (a).

17. A washing-away type cosmetic composition which is washed away after application to the skin or hair, which comprises the dispersion of any one of claims 11 to 13.

18. A process for preparing a washing-away type cosmetic composition which is washed away after application to the skin or hair, which comprises mixing the dispersion of any one of claims 11 to 13 with the components of the cosmetic composition other than the dispersion, at not more than 50° C.

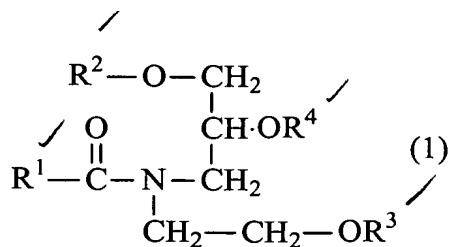
19. A washing-away type cosmetic composition which is washed away after application to the skin or hair comprising:

(A) 0.01 to 10 wt.% of an amphipathic lipid having an average particle size of 0.5 to 150 μm as a solid particulate and having in the molecule thereof, at least one hydroxy group and at least one amide group; and

(b) 5 to 95 wt.% of a surfactant.

20. The dispersion of claim 11, wherein the dispersion is prepared by heating the component (a), the component (b) and water to a temperature not less than the melting point of the component (a), thereby fusing them; and cooling to crystallize the component (a).

21. The dispersion of claim 15, wherein the pseudo-ceramide is an amide derivative represented by the formula (1)



wherein R¹ and R² are the same or different and each independently represents a linear or branched, saturated or unsaturated C₇₋₃₉ hydrocarbon group which may be substituted by at least one hydroxyl group, and R³ and R⁴ are the same or different and each independently

represents a hydrogen atom, a phosphate salt residue, a sulfate salt residue or a saccharide residue, with the proviso that at least one hydroxyl group is contained in the molecule.